

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

IN RE APPLICATION: Michael I. BUKRINSKY, et al.

GROUP ART UNIT: 1614

SERIAL NUMBER: 10/660,748

EXAMINER:

FILED: September 12, 2003

FOR: COMPOUNDS AND METHODS OF USE TO TREAT INFECTIOUS DISEASES



INFORMATION DISCLOSURE STATEMENT UNDER 37 C.F.R. 1.97

Assistant Commissioner for Patents
PO BOX 1450
ALEXANDRIA, VA 22313-1450

Sir:

Applicant(s) wish(es) to disclose the following information.

REFERENCES

- Applicant(s) wish(es) to make of record the documents listed on the attached Form PTO-1449. Copies of the listed documents were previously submitted in parent application Serial No. 09/887,020, filed June 25, 2001, now U.S. Patent No. 6,649,797. References AA-AC are not provided as the present application was filed after June 30, 2003.

RELATED CASES

- Attached is a list of Applicant's(s') pending applications and issued patents which may be related to the present application. Copies of the documents, where required, are attached along with Form PTO-1449.

CERTIFICATION

The undersigned certifies that

- ☐ each item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application for the first time (to the knowledge of the undersigned, having made reasonable inquiry) not more than three months prior to the filing of this statement.
- ☐ no item of information contained in this Information Disclosure Statement was cited in a communication from a foreign or international patent office in a counterpart foreign or international application or, to the knowledge of the undersigned, having made reasonable inquiry, was known to any individual designated in 37 C.F.R. 1.56(c) more than three months prior to the filing of this statement.

BASIS FOR CONSIDERATION

This Information Disclosure Statement is filed:

- ☐ without fee and within three months of the filing date of the application.
- ☐ without fee and within three months of the date of entry of the U.S. national stage.
- without fee and before the mailing date of a first Office Action on the merits (to the knowledge of the undersigned).
- ☐ without fee and with the appropriate certification above.
- ☐ without fee and with a new CPA application.
- ☐ without fee and with a Request for Continued Examination.

DEPOSIT ACCOUNT

- Please charge any additional fees for the papers being filed herewith and for which no check is enclosed herewith, or credit any overpayment to Deposit Account No. 50-1442.

Respectfully submitted,

PIPER RUDNICK LLP

A handwritten signature in black ink, appearing to read "S. Kelber", written over a horizontal line.

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DOCKET NO.: 9511-108-27 CONT



LIST OF RELATED CASES

Docket Number	Serial or Patent Number	Filing or Issue Date	Status or Patentee
9511-008-27	6,297,253	October 2, 2001	Patented
9411-044-27 CIP	5,840,893	November 24, 1998	Patented
9511-084-27 CONT	6,649,797	November 18, 2003	Patented
*9511-108-27 CONT	10/660,748	September 12, 2003	Pending

The cases listed on this Notice of Related Cases include cases which may contain information that is material to patentability. The listing of a case on this Notice should not be taken as an indication or admission that any information contained therein is material. Prior art for each case listed on this Notice may have been cited. **The files corresponding to the listed cases, which are available to the Examiner, may not have not been examined to ascertain the materiality of any prior art therein.** Accordingly, the Examiner is requested to review the file for each case listed on this Notice in order to assess the materiality of such prior art.

*Present application; listed for information.

Form PTO 1449 (Modified)		U.S. DEPARTMENT OF COMMERCE PATENT AND TRADEMARK OFFICE		DOCKET NO. 9511-108-27 CONT		SERIAL NO. 10/660,748	
LIST OF REFERENCES CITED BY APPLICANT (Use Several Sheets if Necessary)				APPLICANT Michael I. Bukrinsky, et al.			
				FILING DATE September 12, 2003		GROUP ART UNIT 1614	
U.S. PATENT DOCUMENTS							
EXAMINER INITIAL	AA	DOCUMENT NUMBER	DATE	NAME	CLASS	SUB CLASS	FILING DATE IF APPROPRIATE
	AA	6,297,253	10/02/01	Bukrinsky, et al.			
	AB	5,840,839	11/24/98	Wang et al.			
	AC	6,649,797	11/18/03	Bukrinsky, et al.			
	AD	5,574,040	11/12/96	Bukrinsky, et al.			
	AE	5,620,983	04/15/97	Bukrinsky, et al.			
	AF	5,703,086	12/30/97	Bukrinsky, et al.			
	AG	5,733,932	03/31/98	Bukrinsky, et al.			
	AH	5,808,068	09/15/98	Pan, et al.			
	AI	5,840,305	11/24/98	Bukrinsky, et al.			
	AJ	5,840,893	11/24/98	Bukrinsky, et al.			
	AK	5,849,793	12/15/98	Pan, et al.			
FOREIGN PATENT DOCUMENTS							
		DOCUMENT NUMBER	DATE	COUNTRY	TRANSLATION YES NO		
OTHER REFERENCES (Including Author, Title, Date, Pertinent Pages, Etc.)							
	BA	Kalderon, et al., "A Short Amino Acid Sequence Able to Specify Nuclear Location", Cell, 39, 499-509 (1984 - Part 2).					
	BB	Dingwall, et al., "The Nucleoplasmin Nuclear Location Sequence is Larger and More Complex than that of SV-40 Large T Antigen", J. Cell Biol., 107, 841-849 (1988).					
	BC	Yeh, et al., "The Arginine-Rich Domain of Hepatitis B Virus Precore and Core Proteins Contains a Signal for Nuclear Transport", J. Virol., 64, 12, 6141-6147 (1990).					
	BD	Zacksenhaus, et al., "A Bipartite Nuclear Localization Signal in the Retinoblastoma Gene Product and Its Importance for Biological Activity", Mol. Cell. Biol., 13, 8, 4588-4599 (1993).					

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			Michael I. Bukrinsky, et al.	
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	BF	Bukrinsky, et al., "A Nuclear Localization Signal Within HIV-1 Matrix Protein that Governs Infection of Non-Dividing Cells", Nature, 365, 666-669 (1993).		
	BG	Goldfarb, et al., "Synthetic Peptides as Nuclear Localization Signals", Nature, 322, 641-644 (1986).		
	BH	Lanford, "Induction of Nuclear Transport with a Synthetic Peptide Homologous to the SV40 T Antigen Transport Signal", Cell, 46, 575-582 (1986).		
	BI	Adam, et al., "Identification of Specific Binding Proteins for a Nuclear Location Sequence", Nature, 337, 276-279 (1989).		
	BJ	Robbins, et al., "Two Interdependent Basic Domains in Nucleoplasmin Nuclear Targeting Sequence: Identification of a Class of Bipartite Nuclear Target Sequence", Cell, 64, 615-623 (1991).		
	BK	Görlich, et al., "Two Different Subunits of Importin Cooperate to Recognize Nuclear Localization Signals and Bind Them to the Nuclear Envelope", Curr. Biol., 5, 4, 383-392 (1995).		
	BL	Radu, et al., "Identification of a Protein Complex that is Required for Nuclear Protein Import and Mediates Docking of Import Substrate to Distinct Nucleoporins", Proc. Natl. Acad. Sci., 92, 1769-1773 (1995).		
	BM	Adam, et al., "Cytosolic Proteins that Specifically Bind Nuclear Location Signals are Receptors for Nuclear Import", Cell, 66, 837-847 (1992).		
	BN	Rexach, et al., "Protein Import Into Nuclei: Association and Dissociation Reactions Involving Transport Substrate, Transport Factors, and Nucleoporins", Cell, 83, 683-692 (1995).		
	BO	Moore, et al., "Purification of a Ran-Interacting Protein that is Required for Protein Import into the Nucleus", Proc. Natl. Acad. Sci., 91, 10212-10216 (1994).		
	BP	Nerhbass, et al., "Role of the Nuclear Transport Factor p10 in Nuclear Import", Science, 272, 120-122 (1996).		
	BQ	Dabauvalle, et al., "Inhibition of Nuclear Accumulation of Karyophilic Proteins in Living Cells by Microinjection of the Lectin Wheat Germ Agglutinin", Exp. Cell Res., 174, 291-296 (1988).		
	BR	Sterne-Marr, et al., "O-Linked Glycoproteins of the Nuclear Pore Complex Interact with a Cytosolic Factor Required for Nuclear Protein Import", J. Cell Biol., 116, 2, 271-280 (1992).		

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			Michael I. Bukrinsky, et al.	
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	BS	Melchior, et al., "Inhibition of Nuclear Protein Import by Nonhydrolyzable Analogues of GTP and Identification of the Small GTPase Ran/TC4 as an Essential Transport Factor", J. Cell Biol., 123, 6, Part 2, 1649-1656 (1993).		
	BT	Weinberg, et al., "Productive Human Immunodeficiency Virus Type 1 (HIV-1) Infection of Nonproliferating Human Monocytes", J. Exp. Med., 174, 1477-1482 (1991).		
	BU	Humphries, et al., "Requirement for Cell Division for Initiation of Transcription of Rous Sarcoma Virus RNA", J. Virol., 14, 3, 531-546 (1974).		
	BV	Stevenson, et al., "HIV-1 Replication is Controlled at the Level of T Cell Activation and Proviral Integration", EMBO J., 9, 5, 1551-1560 (1990).		
	BW	Bukrinsky, et al., "Quiescent T Lymphocytes as an Inducible Virus Reservoir in HIV-1 Infection", Science, 254, 423, Science (1991).		
	BX	Zack, et al., "Incompletely Reverse-Transcribed Human Immunodeficiency Virus Type 1 Genomes in Quiescent Cells Can Function as Intermediates in the Retroviral Life Cycle", J. Virol., 66, 3, 1717-1725 (1992).		
	BY	Schnittman, et al., "The Reservoir for HIV-1 in Human Peripheral Blood is a T Cell That Maintains Express of CD4", Science, 245, 305-308 (1989).		
	BZ	Brinchmann, et al., "Few Infected CD4 ⁺ T Cells but a High Proportion of Replication-Competent Provirus Copies in Asymptomatic Human Immunodeficiency Virus Type 1 Infection", J. Virol., 65, 4, 2019-2023 (1991).		
	CA	Chapel, et al., "Differential Human Immunodeficiency Virus Expression in CD4 ⁺ Cloned Lymphocytes: From Viral Latency to Replication", J. Virol., 66, 6, 3966-3970 (1992).		
	CB	Keonig, et al., "Detection of AIDS Virus in Macrophages in Brain Tissue from AIDS Patients with Encephalopathy", Science, 233, 1089-1093 (1986).		
	CC	Wiley, et al., "Cellular Localization of Human Immunodeficiency Virus Infection Within the Brains of Acquired Immune Deficiency Syndrome Patients", Proc. Natl. Acad. Sci., 83, 7089-7093 (1986).		
	CD	Price, et al., "The Brain in AIDS: Central Nervous System HIV-1 Infection and AIDS Dementia Complex", Science, 239, 586-592 (1988).		
	CE	Giulian, et al., "Secretion of Neurotoxins by Mononuclear Phagocytes Infected with HIV-1", Science, 250, 1593-1596 (1990).		
	CF	Fauci, et al., "Immunopathogenic Mechanisms in Human Immunodeficiency Virus (HIV) Infection", Ann. Int. Med., 114, 8, 678-693 (1991).		

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	CG	Weiss, "How Does HIV Cause AIDS?", Science, 260, 1273-1279 (1993).		
	CH	Pantaleo, et al., "HIV Infection is Active and Progressive in Lymphoid Tissue During the Clinically Latent Stage of Disease", Nature, 362, 355-358 (1993).		
	CI	Zack, "HIV-1 Entry Into Quiescent Primary Lymphocytes: Molecular Analysis Reveals a Labile, Latent Viral Structure", Cell, 61, 213-222 (1990).		
	CJ	Spina, et al., "The Importance of nef in the Induction of Human Immunodeficiency Virus Type 1 Replication from Primary Quiescent CD4 Lymphocytes", J. Exp. Med., 179, 115-113 (1994).		
	CK	Miller, et al., "The Human Immunodeficiency Virus-1 nef Gene Product: A Positive Factor for Viral Infection and Replication in Primary Lymphocytes and Macrophages", J. Exp. Med., 101-113 (1994).		
	CL	von Schwedler, et al., "The Nuclear Localization Signal of the Matrix Protein of Human Immunodeficiency Virus Type 1 Allows the Establishment of Infection in Macrophages and Quiescent T Lymphocytes", Proc. Natl. Acad. Sci., 91, 6992-6996 (1994).		
	CM	Brown, et al., "Correct Integration of Retroviral DNA in Vitro", Cell, 49, 347-356 (1987).		
	CN	Emerman, et al., "HIV-1 Infection of Non-Dividing Cells", Nature, 369, 107-108 (1994).		
	CO	Heinzinger, et al., "The Vpr Protein of Human Immunodeficiency Virus Type 1 Influences Nuclear Localization of Viral Nucleic Acids in Nondividing Host Cells", Proc. Natl. Acad. Sci., 91, 7311-7315 (1994).		
	CP	Gulizia, et al., "Reduced Nuclear Import of Human Immunodeficiency Virus Type 1 Preintegration Complexes in the Presence of a Prototypic Nuclear Targeting Signal", J. Virol. 68, 3, 2021-2025 (1994).		
	CQ	"Malaria", Tropical Diseases, Progress in Research 1989-1990, World Health Organization, pp. 29-40 (1991). (page number incorrectly cited as 15-27 in specification at page 8, line 4)		
	CR	Nosten, et al., "New Antimalarials, A Risk-Benefit Analysis", Drug Safety, 12, 4, 264-273 (1995).		
	CS	Rabjohn, "Selenium Dioxide Oxidation", Org. React., Chapter 4, 261-415 (1976).		
	CT	March, Advanced Organic Chemistry, 4 th ed., Wiley Interscience, New York, 491-493 (1992).		

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	CU	Fenton, et al., "Metal Complexes of 1,1,-[1,3-Phenylene]-bis-1,3-Butanedione", Inorg. Chim. Acta, 44, L105-L106 (1980).		
	CV	Gordon, et al., "Applications of Combinatorial Technologies to Drug Discovery. 2. Combinatorial Organic Synthesis, Library Screening Strategies, and Future Directions", J. Med. Chem., 37, 10, 1385-1401 (1994).		
	CW	Chen, et al., "'Analogous' Organic Synthesis of Small-Compound Libraries: Validation of Combinatorial Chemistry in Small-Molecule Synthesis", J. Amer. Chem. Soc., 116, 2661-2662 (1994).		
	CX	Cho, et al., "An Unnatural Biopolymer", Science, 261, 1303-1305 (1993).		
	CY	Bukrinsky, et al., "Active Nuclear Import of Human Immunodeficiency Virus Type 1 Preintegration Complexes", Proc. Natl. Acad. Sci., 89, 6580-6584 (1992).		
	CZ	Desjardins, et al., "Quantitative Assessment of Antimalarial Activity In Vitro by a Semiautomated Microdilution Technique", Antimicrob. Ag. Chemother., 16, 6, 710-718 (1979).		
	DB	Ager, Jr., Handbook of Experimental Pharmacology, Antimalarial Drugs I, Peters, et al., eds., Chapter 8, Volume 68, Part 1, 225-264, Springer-Verlag, Berlin (1984).		
	DB	Bukrinsky, et al., "Regulation of Nitric Oxide Synthase Activity in Human Immunodeficiency Virus Type 1 (HIV-1)-infected Monocytes: Implications for HIV-Associated Neurological Disease", J. Exp. Med., 181, 735-745 (1995).		
	DC	Ulrich, et al., "Trypanocidal 1,3-Arylene Diketone Bis(guanylhydrazones). Structure-Activity Relationships Among Substituted and Heterocyclic Analogues", J. Med. Chem., 27, 35-40 (1983).		
	DD	McKinnon, et al., "Studies on Some 2,1-Benzisoxazole Derivatives", Can. J. Chem., 49, 2019-2022 (1971).		
	DF	Gartner, et al., "The Role of Mononuclear Phagocytes in HTLV-III/LAV Infection", Science, 233, 215-219 (1986).		
	DF	Nuovo, et al., "Rapid In Situ Detection of PCR-Amplified HIV-1 DNA", Diagn. Mol. Pathol., 1, 2, 98-102 (1992).		
	DG	Chou, "Derivation and Properties of Michaelis-Menten Type and Hill Type Equations for Reference Ligands", J. Theor. Biol., 59, 253-276 (1976).		
	DH	Berger, et al., "Primary and Secondary Metabolism of Pentamidine by Rats", Antimicrob. Ag. Chemother., 36, 9, 1825-1831 (1992).		

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	DI	Westervelt, et al., "Macrophage Tropism Determinants of Human Immunodeficiency Virus Type 1 In Vivo", J. of Virol., 66, 4, 2577-2582 (1992).		
	DJ	Haffar, et al., "Human Immunodeficiency Virus-Like, Nonreplicating, gag-env Particles Assemble in a Recombinant Vaccinia Virus Expression System", J. Virol., 64, 6, 2653-2659 (1990).		
	DK	Chandraratna et al., Chemical Abstracts, Vol. 119:270992, 1993.		
	DL	Porter et al., Chemical Abstracts, Vol. 117:90296, 1992.		
	DM	Reisdorff et al., Chemical Abstracts, Vol. 87:147051, 1977.		
	DN	Barnish et al., Chemical Abstracts, Vol. 87:5796, 1977.		

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